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ETHICS, THE NATIONAL BIOETHICS ADVISORY COMMISSION'S REPORT ON RESEARCH INVOLVING THE MENTALLY DISORDERED, AND THERAPEUTIC JURISPRUDENCE

*Paul A. Nidich**

INTRODUCTION

Anyone interested in the general field of biomedical research ethics will have hundreds, perhaps thousands, of articles, books, editorials, reports, codes, court cases, and more to read, consult, and evaluate. Some tend to be absolutist in nature: a) all research is acceptable, as long as the researcher doesn't lie to or coerce the subject;¹ or b) it is not possible to conduct clinical research in an ethical manner.² The great majority, however, seem to fall in the middle.³ They accept "informed consent"⁴ as

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Special thanks go to Shelley Evans, M.A., M.Ed., Certified Clinical Research Coordinator, for her unceasing efforts at editing earlier drafts of this article and her insistence that I say what I mean and mean what I say.

¹See, generally, Kevin M. King, *A Proposal For the Effective International Regulation of Biomedical Research Involving Human Subjects*, 3 STAN. J. INT'L L. 163 (1998); Karen Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157 (1998).

²See King, *supra* note 1; Morin, *supra* note 1.

³See King, *supra* note 1; Morin, *supra* note 1.

⁴"Informed consent" is placed in quotation marks to indicate that there exists no generally accepted definition of this term, at least in the context of medical research. There are some accepted characteristics, but no generally accepted definition has yet emerged. For an interesting look at the practice of law, lawyers, and the "informed consent" of clients, *see*,

the touchstone of ethical research, but are at odds regarding exceptions, probably basing their opinions on individual professional background or philosophical or religious orientation.⁵

The first part of this article discusses some of the background of current clinical ethics debate and some of the National Bioethics Advisory Commission's (NBAC's or the Commission's) report—*Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*. Part one of this article points out some of the inconsistencies of governmental and Supreme Court views of ethical actions, and some of the therapeutic jurisprudential implications of two of the Commission's recommendations. The second part of this article suggests discarding the current search for the perfect informed consent form or capacity assessment instrument and replacing these efforts with a more productive, therapeutic effort.

BACKGROUND

Ileana Dominguez-Urban quoted from Justice Louis Brandeis' dissenting opinion in *Olmstead v. United States*,⁶ in criticizing the idea of leaving informed consent and competency determinations to the conscience and beneficence of scientists and doctors: "[the] greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding."⁷ Justice Brandeis' statement does not just apply to scientists and doctors. It is equally applicable to many who write in this field, including academicians, attorneys, and bioethicists.

generally, William H. Simon, *Lawyer Advice and Client Autonomy: Mrs. Jones's Case*, 50 MD. L. REV. 213 (1991).

⁵I challenge approving the avoidance of "ethical" mandates on any grounds other than where there is a conflicting ethical mandate. Ethics should not give way to practicality; and where an ethical mandate does, it probably means that the construct was not of an ethical nature in the first place. Elyn R. Saks, *Competency to Refuse Psychotropic Medication: Three Alternatives to the Law's Cognitive Standard*, 47 U. MIAMI L. REV. 689, 761 n.3 (1993) ("As a theoretical matter, we should require competency for consent as well as refusal. But as a practical matter, we should not,..."). I thank Joseph Hathaway, Th.D., clients' rights advocate at the Pauline Warfield Lewis Center, for the many lively discussions we had about both theoretical and practical ethics in the last five years. These helped me test and arrive at some conclusions on these important topics.

⁶See *Olmstead v. United States*, 277 U.S. 438, 479 (1928).

⁷See Ileana Dominguez-Urban, *Harmonization in the Regulation of Pharmaceutical Research and Human Rights: The Need to Think Globally*, 30 CORNELL INT'L L.J. 245, 271 (1997).

Without having spent time in mental health hospitals or on inpatient psychiatric units, an author's notion of the mentally disordered and of research on the mentally disordered may well be inaccurate and to which we may apply the term "sanism."⁸ In this case, the lack of "understanding" Justice Brandeis decried in *Olmstead*, is likely to play a significant part in an author's approach to research ethics. The reader is entitled to know what the author's experiences are, as this should affect the weight a reader gives to that author's opinions.

My background and experiences among the mentally disordered include having served as in-house counsel at the Pauline Warfield Lewis Center, a state mental health hospital in Cincinnati, Ohio, from February 1994 through April 1997. The Lewis Center serves long-term patients, a modest number of acute patients, restoration to competency patients, and those found not guilty by reason of insanity but not deemed dangerous enough to require a "maximum security" mental health facility. While there, I attended civil commitment hearings on a regular basis, served on the hospital's forensics and ethics committees, among others, and I was occasionally invited to attend and participate in discussions of the hospital's Institutional Review Board (IRB). I was frequently consulted by staff psychiatrists about patients' capacity to give informed consent for treatment, their competency to stand trial, and other patient-oriented issues. In doing my job, I met and talked with dozens of patients and got to know many of them.

From April 1997 until the present, my office has been located in the Department of Psychiatry at the University of Cincinnati College of Medicine. From this vantage point, I have gotten to know quite well the psychiatrists, neuroscientists, research assistants, and study coordinators who are responsible for writing the protocols, the informed consent

⁸Michael L. Perlin credits Dr. Morton Birnbaum with coining the term "sanism" to indicate "an irrational prejudice of the same quality and character of other irrational prejudices that cause (and are reflected in) prevailing social attitudes..." Michael L. Perlin, *Half-Wrecked Prejudice Leaped Forth: Sanism, Pretextuality, and Why and How Mental Disability Law Developed as it Did*, 10 J. CONTEMP. LEGAL ISSUES 3, fn. 15 (1999). Professor Perlin has written voluminously on the issue of "sanism." See, e.g., Michael L. Perlin, "Big Ideas and Distorted Facts" *The Insanity Defense, Genetics, and the "Political World"*, in Jeffrey R. Botkin, ed., GENETICS AND CRIMINALITY: THE POTENTIAL MISUSE OF SCIENTIFIC INFORMATION IN COURT 37 (1999); Michael L. Perlin, MENTAL DISABILITY LAW: CIVIL AND CRIMINAL, SECOND EDITION 2D-2 and footnotes contained therein (1998); Michael L. Perlin, *The Jurisprudence of the Insanity Defense*, in DAVID B. WEXLER AND BRUCE J. WINICK, eds., LAW IN A THERAPEUTIC KEY 59 (1996).

documents, and screening individuals for participation in research projects. These experiences certainly have given me the opportunity to develop the kind of understanding needed to avoid the "insidious encroachment" on rights about which Justice Brandeis warned.⁹

The National Bioethics Advisory Commission

On October 3, 1995, President Bill Clinton signed Executive Order 12975 entitled *Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission*.¹⁰ One of the functions of the Commission was to "identify broad principles to govern the ethical conduct of research...."¹¹ Over a period of eighteen months the NBAC studied protections relating to persons with mental disorders.¹²

In a letter dated January 8, 1999, addressed to President Clinton, Harold T. Shapiro, Ph.D., Chair of the NBAC, transmitted NBAC's report and recommendations regarding *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*.¹³ In his letter to President Clinton, Dr. Shapiro told the President that while

⁹See *Olmstead*, 277 U.S. at 479.

¹⁰See Exec. Order No. 12,975, 60 Fed. Reg. 52,063, 52,063-65 (1995).

¹¹*Id.*

¹²See National Bioethics Advisory Commission, *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity* <<http://bioethics.gov/capacity/TOC.htm>> [hereinafter *Research Involving Persons with Mental Disorders*]; *Joint Hearing on Suspension of Medical Research at West Los Angeles and Sepulveda VA Medical Facilities and Informed Consent and Patient Safety in VA Medical Research Before the Subcommittee on Oversight and Investigations and the Subcommittee on Health, Committee on Veterans Affairs, United States House of Representatives*, (April 21, 1999) (Testimony of Eric M. Meslin, Ph.D., Executive Director, National Bioethics Advisory Commission) <<http://veterans.house.gov/hearings/schedule106/apr99/4-21-99J/meslin.htm>> [hereinafter *Veterans Affairs Hearing*].

By reading the statements of the Committee Chair, Representative Terry Everett; Paul Appelbaum, M.D., on behalf of the American Psychiatric Association; and others who testified on that day, the hearing was prompted by reports that research was conducted on four cardiology patients without first obtaining any kind of consent and, indeed, even over the objection of one of the patients. See *Opening Statement of the Committee Chair*, Terry Everett, <<http://veterans.house.gov/hearings/schedule106/apr99/4-21-99J/everopen.htm>>; *Testimony of the American Psychiatric Association* (statement of Paul Appelbaum, M.D.) <<http://veterans.house.gov/hearings/schedule106/apr99/4-21-99J/apa.htm>>. Thus, the hearing was about the outrage regarding the failure to follow existing regulations, not the need to protect research subjects through additional federal regulations.

¹³See Letter from Harold T. Shapiro, Ph.D., *Chair of the National Bioethics Advisory Commission*, to President Clinton 1 (Jan. 8, 1999) in *NBAC Report*, *supra* note 12, at unnumbered page 3.

"existing federal regulations for research involving human subjects has provided special protections for certain populations that are regarded as particularly vulnerable, persons with mental disorders who may have impaired capacity to make decisions, and therefore to give voluntary informed consent, have not received any such special protections."¹⁴ Dr. Shapiro further commented in his transmittal letter that "[The Commission] believes that enhanced protections will promote broad-based support for further research by engendering greater public trust and confidence that subjects' rights and interests are fully respected."¹⁵ In the Executive Summary of its report, the Commission wrote:

NBAC believes that a cogent case can be made for requiring additional special protections in research involving as subjects persons with impaired decisionmaking capacity, but has chosen to focus this report on persons with mental disorders, in part because of this population's difficult history of involvement in medical research.¹⁶

In Chapter One of its report, "An Overview of the Issues," NBAC made two startling admissions about its investigation. The Commission noted that there was no crisis in this area, only "confusion about the principles and procedures that should govern" clinical research involving the mentally ill.¹⁷ NBAC also noted that the "system" was not "broken;" there was merely "a *perceived gap* in human subjects protection."¹⁸ Indeed, the Commission wrote:

¹⁴*Id.*

¹⁵*Id.* at 2 (emphasis added).

¹⁶*Id.* at iii - iv. One of the early and continuing criticism of this report related to its focus on the mentally ill, thus further stigmatizing this population. The Commission could have chosen to focus on impaired decisionmaking, not on the decision maker. See Hearings Before the National Bioethics Advisory Commission, (1998) (statement of Harold Pinkus, M.D. on behalf of the American Psychiatric Association) <<http://bioethics.gov/transcripts/oct98/public.htm>>. The way Society has chosen to protect certain rights of the mentally ill has also come under criticism. Paul Stavis, in an address to the 1995 National Conference of the National Alliance for the Mentally Ill, noted that to protect patients' rights regarding hospitalization and treatment, the patient must be sued and "stigmatized a dangerous person in some increasingly vague sense of the word." Paul A. Nidich, *Zinermon v. Burch and Voluntary Admissions to Public Hospitals: A Common Sense Proposal for Compromise*, 25 N. KY. L. R. 699, 712 fn. 79 (1998).

¹⁷Research Involving Persons with Mental Disorders, *supra* note 12, at 3.

¹⁸*Id.* at 2 (emphasis added).

The justification for this report, therefore, is the confluence of several considerations, including *perceived gaps* in the federal system for the protection of human subjects; historical and contemporary cases in which the protection of human subjects *appears* to have been inadequate; and the need to ensure that research designed to develop better treatments for mental disorders can proceed with full public confidence in its ethical framework.¹⁹

The charge the Commission gave itself for this report was to consider "how ethically acceptable research can be conducted with human subjects who suffer from mental disorders that may affect their decisionmaking capacity[.]"²⁰

The Commission's report contains twenty-one recommendations divided into six sections. The first section contains recommendations for review boards and specifically calls for the creation of a "Special Standing Panel" (Panel).²¹ This Panel would address protocols forwarded by IRBs for review where the IRBs did not have the authority to approve a protocol under existing regulations.²² It also would promulgate guidelines so that IRBs could approve protocols not otherwise subject to approval under the Commission's report without having to submit them to the Special Standing Panel.²³

The second section addresses research designs,²⁴ the third addresses "Informed Consent and Capacity,"²⁵ and the fourth section comments on categories of research, *e.g.*, protocols involving minimal risks.²⁶ Surrogate decision making is the subject of the fifth section,²⁷ while the last section discusses "Education, Research, and Support."²⁸

¹⁹*Id.* at 3 (emphasis added).

²⁰*Id.* at 4.

²¹Research Involving Persons with Mental Disorders, *supra* note 12, at iii - iv.

²²*See id.*

²³*See id.*

²⁴*See id.* at iv.

²⁵*See id.* at iv - v.

²⁶*See* Research Involving Persons with Mental Disorders, *supra* note 12, at v.

²⁷*See id.* at v - vi.

²⁸*See id.* at vi - vii.

ANALYSIS

Bioethics: Can It Be Defined or Do You Just Know It When You See It?²⁹

Americans instinctively feel that the United States Constitution and morality go hand-in-hand, but that proposition can easily be discredited. For example, no one today would assert that Article IV, Section 2, Clause 3³⁰ of the Constitution relating to slavery is consistent with today's view of ethics. Nor, for that matter, would one find that the United States Supreme Court has consistently interpreted the Constitution in a way recognized today as ethically beyond reproach.³¹

The concept of research ethics does not have a single, consistent definition that is universally accepted by Western society, much less all societies of the world.³² There is a difference of opinion, for example, about when a new medication should be offered on the market.³³ The

²⁹See *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J. concurring) (referring to Justice Stewart's famous comment about pornography, "perhaps I could never succeed in intelligibly [defining pornography]. But I know it when I see it"). It is not my intent to equate bioethics with pornography, just to dramatically point out that the lack of a common definition of bioethics encourages sanism to dictate what is or is not ethical regarding the mentally disordered.

³⁰See Act of February 12, 1793 (1 Stat. 302). "No Person held to Service of Labour in one State, under the Laws thereof, escaping into another, shall, in Consequence of any Law or Regulation therein, be discharged from such Service of Labour, but shall be delivered upon Claim of the Party to whom such Service of Labour may be due." The purpose of this clause, of course, was to guarantee to the slave-holding states that runaway slaves would not become free simply by entering a state which had outlawed slavery. This clause of the Constitution was implemented by Congress through the Act of February 12, 1793 (1 Stat. 302). For a brief discussion of the impact of slavery and the drafting of the Constitution, see James Brown Scott, *JAMES MADISON'S NOTES OF DEBATES IN THE FEDERAL CONVENTION OF 1787 AND THEIR RELATION TO A MORE PERFECT SOCIETY OF NATIONS* 38 - 44 (1918). See also Charles A. Beard, *AN ECONOMIC INTERPRETATION OF THE CONSTITUTION OF THE UNITED STATES* 151 (1986) ("[a]t least fifteen members" out of fifty-five delegates to the Convention were slave-holders).

³¹See *Prigg v. Pennsylvania*, 41 U.S. (16 Pet.) 539 (1842) (upholding U.S. Const. art. III, § 2, cl. 3.). See also *Hirabayashi v. United States*, 320 U.S. 81 (1943) (addressing Japanese internment during World War II); *Korematsu v. United States*, 323 U.S. 214 (1944) (same). Unlike the shameful Article IV, Section 2, Clause 3 of the Constitution regarding slavery which was abolished, *Hirabayashi* and *Korematsu* still remain good law. See *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200, 215-16 (1995).

³²See Dominguez-Urban, *supra* note 7, at 274 ("Both the [Nuremberg] Code and [the Declaration of Helsinki] have been criticized as too tied to Western principles which are not necessarily applicable to other cultures") (footnote omitted).

³³See *id.* at 260.

French do not require randomized, controlled studies³⁴ before introducing a new medication into the marketplace.³⁵ They consider placebo testing to be "cruel and inhumane."³⁶ On the other hand, the Food and Drug Administration requires randomized trials to ensure the safety and effectiveness of the new medication vis-a-vis other medications already on the market.³⁷

Statements regarding "informed consent," an undefined but often asserted ethical construct, have been found in numerous writings and codes of ethics.³⁸ The NBAC noted that the Nuremberg Code "makes [informed] consent the first and essential requisite of ethical research."³⁹ NBAC further noted that "[v]oluntary, informed consent is normally an essential feature of ethically and acceptable research."⁴⁰ The Office for Protection from Research Risks of the National Institutes of Health noted in its Institutional Review Board Guidebook that "[i]nformed consent is one of the primary ethical requirements underpinning research with human subjects...."⁴¹

The position that informed consent is an ethical requirement in clinical research is also found in numerous law review articles.⁴² In one

³⁴See *id.*

³⁵See *id.*

³⁶*Id.*

³⁷See Dominguez-Urban, *supra* note 7, at 261.

³⁸Research Involving Persons with Mental Disorders, *supra* note 12, at 18.

³⁹*Id.*

⁴⁰*Id.* The phrase "informed consent," lacks a generally accepted definition. See *supra* note 4. There is even less agreement about the definition of "voluntary," especially in the context of an inpatient setting: "[m]oreover, those who are hospitalized in psychiatric units are especially vulnerable by virtue of the unique dynamics of that environment." Research Involving Persons with Mental Disorders, *supra* note 12, at 6. Is the fact that the person is an inpatient (or a prisoner) enough to declare decisions involuntary? When the family becomes involved in the decision-making process of an adult patient, complications can multiply. At what point does family involvement become coercive, thus depriving the patient of the opportunity to make a "voluntary" decision? As Robert J. Levine observed: "[u]nequivocally correct answers are available only to those who believe there is or can be a science of morality." Robert J. Levine, *Medical Ethics and Personal Doctors: Conflicts Between What We Teach and What we Want*, 13 AM. J. L. AND MED. 351, 353 fn. 4 (1987).

⁴¹See OFFICE FOR PROTECTION FROM RESEARCH RISKS, INSTITUTIONAL REVIEW BOARD GUIDEBOOK 7 (1993) <http://grants.nih.gov/grants/opr/irb/irb_chapter3.htm>.

⁴²See Leonard W. Schroeter, *Human Experimentation, the Hanford Nuclear Site, and Judgment at Nuremberg*, 31 GONZ. L. REV. 147, 154 (1995-96).

such article, Leonard W. Schroeter, referring to the Nuremberg Code, stated that:

Violation [of the Nuremberg Code] by a health care provider is unethical and wholly unjustifiable. When done by the government, it was held at Nuremberg to constitute a crime against humanity and a violation of fundamental rights so profound and universal that it could not be accepted by the laws of any civilized nation.⁴³

In another article, George J. Annas trumpeted the import of the Nuremberg Code: "[t]he Nuremberg Code remains the most authoritative legal and ethical document governing international research standards and one of the premier human rights documents in world history."⁴⁴ In this same article Professor Annas decried The Declaration of Helsinki created in 1964 as a document written by physicians and meant "to replace the human rights-based agenda of the Nuremberg Code with a more lenient medical ethics model which permits paternalism."⁴⁵

Matthew Lippman, in an article discussing the prosecution of Nazi doctors, wrote, "[t]hose who intentionally or negligently violate core ethical obligations risk criminal sanction. Central are the requirements of informed consent, professional autonomy, the privacy of the patient, the cultivation of health rather than harm and adherence to process principles."⁴⁶

One must evaluate the above statements of Schroeter, Annas, and Lippman regarding the Nuremberg Code as the foundation of biomedical research ethics in light of the following comments by Richard Garnett:

The focus at Nuremberg was not on the lack of consent given by the Nazis' victims, but on the horrific aspects of the acts themselves...

⁴³*Id.*

⁴⁴George J. Annas, *Questing for Grails: Duplicity, Betrayal and Self-Deception in Postmodern Medical Research*, 12 J. CONTEMP. H.L. & POL'Y 297, 301 (1996).

⁴⁵*Id.* at 303.

⁴⁶Matthew Lippman, *War Crimes Prosecutions of Nazi Health Professionals and the Contemporary Protection of Human Rights*, 21 THUR. MAR. L. REV. 11, 75 (1995).

To focus on consent as the lesson of Nuremberg, and to identify consent as the primary locus for moral concern in human experimentation, misses the point. One commentator has said: "it would be a moral understatement to conclude that the Nazi experiments were wrong because voluntary, informed consent was not obtained from the subjects...."⁴⁷

In short, the Nuremberg Code should not be considered the ethical gold standard solely because it resulted from the atrocities of the Nazis, atrocities that shocked the conscience of the world. The Nuremberg Code must be judged on its own, and that judgment will differ from culture to culture around the world.⁴⁸

In fact, the roots of Adolph Hitler's "Master Race" theory, its subsequent atrocities and objective of exterminating the Jews, was found in⁴⁹ and supported by the American Eugenics movement.⁵⁰ In 1934, the German journal *Volk und Rasse*, published by the German Ministry of the Interior and the German Society for Racial Hygiene, "referred favorably to United States Supreme Court decisions that legitimized compulsory sterilization in 1916 and again in 1927."⁵¹ The Hereditary Health Law, instituted in Germany on July 14, 1933, was based upon the Virginia sterilization law affirmed by the Supreme Court in *Buck v. Bell*,⁵² decided on May 2, 1927.⁵³ The German law resulted in over 56,000 sterilizations in just one year.⁵⁴

⁴⁷Richard Garnett, *Why Informed Consent? Human Experimentation and the Ethics of Autonomy*, 36 CATHOLIC LAW 455, 504 (1996).

⁴⁸See Dominguez-Urban, *supra* note 7, at 268.

⁴⁹See Stefan Kühl, THE NAZI CONNECTION: EUGENICS, AMERICAN RACISM, AND GERMAN NATIONAL SOCIALISM 37 (1994); Erika T. Blum, *When Terminating Parental Rights Is Not Enough: A New Look at Compulsory Sterilization*, 28 GA. L. REV. 977, 981, fn. 29 (1994).

⁵⁰Kühl, *supra* note 49, at 44-48; STEPHEN TROMBLEY, THE RIGHT TO REPRODUCE: A HISTORY OF COERCIVE STERILIZATION Ch. 7 (1988).

⁵¹See *id.* at 38. I have not been able to identify any Supreme Court decision from 1916 to which this may have referred. The Court dismissed as moot the case of *Berry v. Davis*, 242 U.S. 468 (1916), in which an Iowa statute which directed sterilization for criminals twice convicted of felonies was repealed prior to the Court's taking action on the appeal. Perhaps this was the case to which the quote referred.

⁵²See *Buck v. Bell*, 274 U.S. 200 (1927).

⁵³See Carol A. Gaudet, *Linking Genes with Behavior: The Social and Legal Implications of Using Genetic Evidence in Criminal Trials*, 24 FORDHAM URB. L.J. 597, 602 fn 34 (1997).

⁵⁴See *id.*

Buck v. Bell provides an interesting look into the minds of some of America's greatest Supreme Court Justices. Carrie Buck⁵⁵ was an involuntary resident of the Virginia Colony for Epileptics and Feeble-minded.⁵⁶ She was "the daughter of a feeble-minded mother in the same institution, and the mother of an illegitimate feeble-minded child."⁵⁷ According to the facts stated in the opinion by Justice Oliver Wendell Holmes, a Virginia statute provided that the superintendent of state institutions could have an inmate sterilized if the inmate was afflicted with a hereditary form of insanity or imbecility and the superintendent considered it in the best interest of the patient and society.⁵⁸ This decision, though, would have to comply "with the very careful provisions by which the act protects the patients from possible abuse."⁵⁹

Justice Holmes submitted that the process required in the Virginia law to obtain an order for sterilization met due process requirements.⁶⁰ He also rejected the Fourteenth Amendment substantive due process challenge to the statute.⁶¹ Justice Holmes wrote:

We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices, often not felt to be such by those concerned, in order to prevent our being swamped with incompetence...The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes. (Citation omitted). Three generations of imbeciles are enough.⁶²

⁵⁵See TROMBLEY, *supra* note 50, at Ch. 6, *The Ordeal of Carrie Buck*; Paul A. Lombardo, *Medicine, Eugenics, and the Supreme Court: From Coercive Sterilization to Reproductive Freedom*, 13 J. CONTEMP. HEALTH L. & POL'Y 1, 9-12 (1996).

⁵⁶See *Buck*, 274 U.S. at 205.

⁵⁷*Id.*

⁵⁸See *id.*

⁵⁹*Id.* at 206.

⁶⁰See *id.* at 207.

⁶¹See *Buck*, 274 U.S. at 207.

⁶²*Id.* This opinion was signed by seven other Justices, including Justice Brandeis, the author of the dissenting opinion in *Olmstead v. United States*, 277 U.S. 438, 479 (Brandeis, J., dissenting). Only Justice Pierce Butler dissented, but he did so without opinion. See *Buck v. Bell*, 274 U.S. 200, 207 (1927) (Butler, J., dissenting). It should also be noted that *Buck v. Bell* has never been overruled by the Supreme Court, and was cited as authority in *Roe v. Wade*, 410 U.S.

It seems, however, that before one can declare something either ethical or unethical, there must be some agreed upon definition of ethics. Did the authors of the Nuremberg Code have a common, secular definition of ethics? Did NBAC have a clearly expressed definition of ethics shared by all of the Commissioners? If not, are these expressions of ethics truly meaningful, or are they combinations of different opinions held together only by the use of a common, undefined word? As David Weisstub noted:

In the discourse of research ethics committees, there is an almost startling repetition of certain catch phrases: beneficence, respect for persons and justice. Normally, members of such committees are not particularly well informed about the philosophical content surrounding these principles, and it is not clear whether referring to them advances in any significant way the goal of attaining shared moral precepts for making hard decisions.⁶³

Form Over Substance Versus Therapeutic Jurisprudence

Philosophers, among others, have energetically and vigorously debated what the paradigm of ethics should be. Theories of ethics include, *inter alia*, various religions' ethical constructs, perfectionism, ethical relativism, hedonism, pluralism, utilitarianism, and welfare.⁶⁴ Thus, an individual's decision about what is ethical may well be affected by the system or theory of ethics the individual chooses.⁶⁵ By agreeing on

113, 154 (1973), "[t]he privacy right involved [in an abortion decision], therefore, cannot be said to be absolute.... The Court has refused to recognize an unlimited right of this kind in the past. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (vaccination); *Buck v. Bell*, 274 U.S. 200 (1927) (sterilization)." See *Roe*, 410 U.S. at 154. *Buck v. Bell*, was similarly cited by Justice William O. Douglas concurring in *Doe v. Bolton*, 410 U.S. 179, 215 (1973) (Douglas, J., concurring).

⁶³David N. Weisstub, *Roles and Fiction in Clinical and Research Ethics*, 4 HEALTH L.J. 259, 271 (1996).

⁶⁴See ROGER J. BULGER, TECHNOLOGY, BUREAUCRACY, AND HEALING IN AMERICA: A POST MODERN PARADIGM 18 (1988).

⁶⁵For example, the Supreme Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973), required a rejection of orthodox religious ethics. The decision is said to have "delegitimized" Catholic doctrine in the area of abortion. See Stefano Rodot, *Cultural Models and the Future of Bioethics*, 10 J CONTEMP HEALTH L & POL'Y 33, 40 (1994); *Lynch v. Donnelly*, 465 U.S. 668, 694 (1984) (Brennan J., dissenting). *Lynch v. Donnelly*, permitted the City of Pawtucket, Rhode

a benchmark theory of ethics, bioethicists can defend their positions based upon something other than what *feels* right, because something that feels right to a person living in the tradition of a liberal Western society may feel totally wrong to someone living in the tradition of an Asian or African society.⁶⁶

The innumerable discussions of who, when, and how to determine, in minute detail, whether an individual has the capacity to make a voluntary, informed consent decision to participate in research is a quintessential argument of form over substance.⁶⁷ The more telling issue is the impact of NBAC's recommendations on the patient/subject-doctor/researcher relationship. For that, we turn to the developing field of therapeutic jurisprudence.

Therapeutic jurisprudence is a name given to a particular philosophy of studying law and law-related activities.⁶⁸ It is the study of the role of law as a therapeutic agent, a way to explore how the insights of mental health and related disciplines can help to influence the continuing evolution of our legal system along lines that are beneficial to the physical or psychological well-being of the people that particular laws, regulations, or systems affect.⁶⁹ By applying a therapeutic jurisprudence evaluation to the NBAC recommendations, one can arrive at a decision of whether the recommendations are, indeed, consistent with ethical medical research.⁷⁰

Recommendations eight and nine read:

Island, to include a creche in its annual Christmas display. Dissenting, Justice Brennan noted, "[b]y insisting that such a distinctively sectarian message is merely an unobjectionable part of our 'religious heritage,'...the Court takes a long step backwards to the days when Justice Brewer could arrogantly declare for the Court that 'this is a Christian nation' (citations omitted)." *Lynch*, 465 U.S. at 717-18. One can only wonder if the decision would have been different had the composition of the Court been different.

⁶⁶See Rodot, *supra* note 65; Dominguez-Urban, *supra* note 7.

⁶⁷See Weisstub, *supra* note 63, at 278 ("But even [the staunchest supporters] are forced to admit that short of thoroughly integrating the doctrine into a meaningful process of exchange that is reflected in the ethos of medicine, the law of informed consent is destined to remain nothing more than a fairy tale").

⁶⁸See David B. Wexler and Bruce J. Winick, eds., *LAW IN A THERAPEUTIC KEY* XVII (1996).

⁶⁹See *id.*

⁷⁰Because of time and space constraints, I propose to evaluate only recommendations eight and nine. Others, however, may pursue such evaluations with other recommendations which are of a controversial or seemingly anti-therapeutic nature, especially Recommendation 2, the Special Standing Panel.

[Recommendation 8] For research protocols that present greater than minimal risk,⁷¹ an IRB should require that an independent, qualified professional assess the potential subject's capacity to consent. The protocol should describe who will conduct the assessment and the nature of the assessment. An IRB should permit investigators to use less formal procedures to assess potential subjects' capacity if there are good reasons for doing so.⁷²

[Recommendation 9] A person who has been determined to lack capacity to consent to participate in a research study must be notified of that determination before permission may be sought from his or her legally authorized representative (LAR) to enroll that person in the study. If permission is given to enroll such a person in the study, the potential subject must then be notified. Should the person object to participating, this objection should be heeded.⁷³

These two recommendations must be read together, as they are functionally related. On their face, they require that "an independent, qualified professional assess the potential subject's capacity to consent" and then require that the potential subject "be notified of that determination."⁷⁴ The potential consequences of this process were noted by the Commission in its report:

⁷¹The term "minimal risk" is defined by the Common Rule, 45 C.F.R. § 46.102(i) (1999), as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Research Involving Persons with Mental Disorders, *supra* note 12, at 40-44. The Commission, however, does make clear that the "daily life" standard is not a subjective standard. *See id.* The Commission insists that any risk encountered in research greater than that encountered in the daily lives of the general population be considered in the category of greater than minimal risk. *See id.* at 43.

⁷²Research Involving Persons with Mental Disorders, *supra* note 12, at 43.

⁷³*Id.*

⁷⁴*Id.* One might argue that it is unfair to take the recommendations at face value, because the Commission report contains many caveats. The Commission stated, for example, that "IRBs should generally require investigators to assess whether potential subjects have the capacity to give voluntary, informed consent" in its comments following recommendation eight. *Id.* at 59 (emphasis added). This is not consistent with the actual language of Recommendation 8.

The Commission's report, when read in its entirety, demonstrates that the Commission

Because of their moral consequences, incorrect capacity determinations can be inadvertently damaging—an assessment that a capable person is incapable of exercising autonomy is disrespectful, demeaning, and stigmatizing....⁷⁵

From a therapeutic jurisprudence point of view, the consequences of an incorrect capacity assessment are more damaging—they are anti-therapeutic. The person who was willing to volunteer is now deprived of any psychological or other benefit, which prompted him to volunteer in the first place. This is especially true of the person who was willing to volunteer primarily out of a sense of contributing to the welfare of others. The volunteer is now robbed of that altruistic feeling of value because of his willingness to make a contribution to society.⁷⁶ Another negative therapeutic outcome is that capacity assessments conducted by independent professionals may be confusing to an inpatient and cast doubt in the patient's mind about the professional stature and quality of the professionals taking care of him.⁷⁷ Additionally, the recommendations assume one of two degrees of inter-rater reliability.⁷⁸

doesn't really stand behind a literal reading of its recommendations; the recommendations must be interpreted and applied by reading the whole report. Are the departments who are exhorted to amend their regulations regarding medical research supposed to adopt the recommendations but not apply them as written? Are they to wrestle with creating rules which combine both what the recommendations say and what they were meant to say, something the Commission was apparently unwilling to do?

⁷⁵*Id.* at 20 (citing Elyn R. Saks, *Competency to Decide on Treatment and Research: The MacArthur Capacity Instruments*, in *Research Involving Persons with Mental Disorders*).

⁷⁶In the final analysis, genuine human society is characterized as a community of individuals united for the purpose of constituting a moral commonwealth. See Jane Kneller, *Introducing Kantian Social Theory*, in *AUTONOMY AND COMMUNITY: READINGS IN CONTEMPORARY KANTIAN SOCIAL PHILOSOPHY* 11 (Jane Kneller & Sidney Axinn, eds. 1998).

⁷⁷One could easily envision some inpatients wondering what was wrong with their own psychiatrists, since someone else, presumably better qualified professionally, conducted this assessment.

⁷⁸See R. BARKER BAUSELL, *A PRACTICAL GUIDE TO CONDUCTING EMPIRICAL RESEARCH* 190 (1986) (describing inter-rater reliability. Inter-rater reliability is critical for performance-based assessment. It is an estimate of the consistency of the scores assigned by two or more raters. High inter-rater reliability indicates that the raters used the same criteria to evaluate a performance, and that they understood and applied the criteria similarly.).

If there were a high degree of inter-rater reliability, currently a weak assumption,⁷⁹ the purpose of the independent assessment would be negated. On the other hand, if there were a low degree of inter-rater reliability, no research would likely take place involving persons addressed by the recommendations.

There are other anti-therapeutic consequences to incompetency labeling.⁸⁰ In an article entitled *The Side Effects of Incompetency Labeling and the Implications for Mental Health Law*,⁸¹ Bruce Winick noted several other anti-therapeutic effects of incorrectly labeling someone as incompetent:

The individual's perceptions of noncontrol become linked with low expectations concerning success, fostering feelings of helplessness and hopelessness....⁸²

Labeling mentally ill individuals as incompetent may thus be devastating, diminishing self-esteem and inhibiting future performance. Even more than labeling such persons as mentally ill, labeling them as incompetent may produce or perpetuate learned helplessness....⁸³

⁷⁹See Daniel C. Marson, *Consistency of Physician Judgment of Capacity to Consent in Mild Alzheimer's Disease*, 45 J. OF AMERICAN GERIATRIC SOCIETY 453-57 (1997) (finding a 98 percent inter-rater reliability in assessing the control group but only 56 percent agreement on the capacity of the Alzheimer test population).

⁸⁰Society's interchangeable use of the terms "capacity to consent" and "competency" leaves no reason to doubt that patients will most often be told that they are "incompetent" to make decisions, not that they "lack the capacity to make a voluntary informed consent decision to participate in research." In addition to the terms "informed consent," "ethics," and "voluntary," the term "competency" can also be added to the list of critical terms that lack a precise definition. Elyn R. Saks & Stephen H. Behnke, *Competency to Decide on Treatment and Research: MacArthur and Beyond*, 10 J. CONTEMP. LEGAL ISSUES 103, 105-06 (1999). Robert Michels suggested that there was a "traditional definition of the capacity to consent to research," but this really was a set of conditions and not a definition. Robert Michels, *Are Research Ethics Bad for Our Mental Health?*, 340 N ENGL J MED 1427, 1427-30 (1999).

⁸¹See Bruce J. Winick, *The Side Effects of Incompetency Labeling and the Implications for Mental Health Law*, 1 PSYCH. PUB. POL. AND L. 6, 29 (1995), reprinted in LAW IN A THERAPEUTIC KEY, *supra* note 8, at 17. Professor Winick uses the term incompetent in its broadest sense, including capacity to make informed consent treatment decisions and informal, as well as formal labeling. See *id.*

⁸²*Id.* at 29.

⁸³*Id.* at 32.

The incompetency label predictably produces depression and withdrawal and saps motivation.⁸⁴

The Commission's apparent rationale for ignoring these serious anti-therapeutic consequences and adopting recommendations eight and nine was that "a judgment that an incapable person is capable leaves that subject unprotected and vulnerable to exploitation by others," citing the 1979 *Belmont Report*.⁸⁵ The *Belmont Report* was issued in 1979 when IRBs were in their infancy and more than two decades before NBAC undertook this study. Reliance on the *Belmont Report* to justify its recommendations was inappropriate, because by at least 1987, there was a "broad consensus that our national policy for the 'protection of human subjects' [was] fundamentally sound."⁸⁶ Given all this evidence suggesting that recommendations eight and nine were not necessary and were anti-therapeutic to the very population the Commission was trying to protect, these recommendations should be rejected by the government and the research and bioethics communities.

CONCLUSION AND RECOMMENDATIONS

When one looks through the prism of therapeutic jurisprudence, one is left with the unmistakable conclusion that the NBAC missed the mark in its *Report and Recommendations on Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*. The Commission was acting based upon an inaccurate picture of clinical research in the late 1990s.⁸⁷ Even though the Commission received much written and oral commentary relating to today's research activities, and debated these issues intensely, in the end, it appears that it simply chose to knock down a straw man (the *Belmont Report*) to justify further governmental paternalism in medical research.

⁸⁴*Id.* at 33.

⁸⁵See *Research Involving Persons with Mental Disorders*, *supra* note 12, at 20; *The Belmont Report*, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

⁸⁶Robert J. Levine, *supra* note 40, at 359. Dr. Levine labeled this policy a "success." *Id.*

⁸⁷See *Research Involving Persons with Mental Disorders*, *supra* note 12, at 1.

The Commission began its work on this project acknowledging that there wasn't a problem that needed to be fixed.⁸⁸ It noted that there wasn't a real gap in human subjects' protections, only a *perceived* gap.⁸⁹ It provided no evidence that there was, indeed, a lack of "public confidence" that needed to be addressed.⁹⁰ The recommendations that were addressed in this article, numbers eight and nine, can only be seen as anti-therapeutic and anti-research and should be rejected. The NBAC report and Recommendations were, in the words of Robert Michels, "prescribing a treatment" before "[establishing] a diagnosis."⁹¹

Any system involving humans is only as decent as the people comprising it; no set of rules can dictate everyone's behavior all of the time. How well IRBs work and how sensitive researchers are to *all* research subjects cannot be dictated by layers and layers of federal regulations. This is the essential lesson which should have been learned from the Veterans Affairs Hearing. Education and supervision can help, but the objective should not be to make the informed consent document so lengthy and complicated that consent becomes anything but informed. Current regulations are more than sufficient for protection of human research subjects. Nor should anti-therapeutic independent capacity assessments be encouraged. Before NBAC's recommendations are acted upon any further, and before any new proposals are made, an ethical construct must be agreed upon, a therapeutic jurisprudence analysis done, and all should be held up to the light of "don't do to others what you don't want others to do to you."

Former Chief Justice Earl Warren observed that our society has "evolving standards of decency."⁹² In that vein, I suggest that a new standard of research ethics be adopted, the constitutional due process analysis of "shocks the conscience."⁹³ When viewed against this standard, current regulations regarding research involving humans, such as the Common Rule, 45 C.F.R. Part 46, will either become *rules* that

⁸⁸See *id.* at 2.

⁸⁹See *id.*

⁹⁰See *id.*

⁹¹Robert Michels, *supra* note 81.

⁹²*Trop v. Dulles*, 356 U.S. 86, 101 (1958) (The "evolving standards of decency...mark the progress of a maturing society").

⁹³*Id.*

"shock the conscience" and need to be changed, or their accepted decency will not change. The secular standard of decency and ethics in America today would not be shocked in the following situations.⁹⁴ It would not shock the conscience if the law were followed and the legal presumption of competency were honored rather than tested by capacity assessments conducted by independent assessors.⁹⁵ It would not shock the conscience if researchers, who respect their work and the dignity of research subjects, were to allow individuals to participate in some greater than minimal risk studies based on consent where the individual had a reasonable understanding of what was happening and what was at stake. It would not shock the conscience if well-trained and conscientiously scrupulous IRBs approved protocols that were scientifically sound and permitted less than "perfect" informed consent. "Shocks the conscience" came into our jurisprudence with the Supreme Court's review of the conviction of Antonio Rochin in California.⁹⁶ In reversing the conviction of Rochin, Justice Felix Frankfurter wrote that the actions of the law enforcement officers "shocks the conscience."⁹⁷ Illegally breaking into the privacy of [Rochin], the struggle to open his mouth and remove what was there, the forcible extraction of his stomach's contents—this course of proceeding by agents of the government to obtain evidence is bound to offend even hardened sensibilities, and require a reversal of the conviction.⁹⁸ This, in essence, was the cause for the Veterans Affairs Hearing, conducting

⁹⁴Here I use the word "secular" for lack of a better term. Orthodox religious tenets of ethics are not accepted by a majority of Americans; and while "bioethicists" allow themselves to be informed by Orthodox religions, they cannot afford to seem to be controlled by these minority, Orthodox religions. See Michael R. Moodie, S.J., *Symposium on Religious Law: Roman Catholic, Islamic, and Jewish Treatment of Familial Issues, including Education, Abortion, In Vitro Fertilization, Prenuptial Agreements, Contraception, and Marital Fraud*, 16 LOY. L.A. INT'L & COMP. L.J. 9, 45-46 (1993) (describing the views of various Roman Catholic Priests, Islamic scholars, and Jewish Rabbis regarding these particular issues. In the discussion on abortion, Rabbi Elliot N. Dorff explained that "Jewish law is based on duties, in contrast to the emphasis in American law on individual rights").

⁹⁵See Botkin, *supra* note 8, at 211 ("Our legal system presumes that adults act on their own volition—in other words, with free will—unless it can be proven otherwise").

⁹⁶*Rochin v. California*, 342 U.S. 165, 172 (1952).

⁹⁷*Id.*

research in the face of a denial of consent, a clear violation of existing regulations, certainly shocks the conscience of America.⁹⁹ Furthermore, the argument that Bruce Winick made in suggesting reducing the use of capacity assessments rather than increasing their usage is a compelling one.¹⁰⁰ Only the most obvious and seriously impaired individuals, with or without mental disorders, should be denied the opportunity to participate in medical research.

⁹⁸*See id.* *See also* County of Sacramento v. Lewis, 523 U.S. 833, 846 (1998) (discussing the differences between the deliberate indifference standard for Eighth Amendment liability and the shocks the conscience standard). For the purpose of this article, *i.e.*, determining whether a research protocol satisfies this suggested new standard, deliberate indifference and shocks the conscience can be used interchangeably without practical significance.

⁹⁹*See* WEXLER, *supra* note 8.

¹⁰⁰*See id.*